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The Role of Institutional Review Boards in Aviation Research: It's the Law and It Makes Sense

Dr. Earl S. Stein

THE ROLE OF INSTITUTIONAL REVIEW BOARDS IN AVIATION RESEARCH: IT'S THE LAW AND IT MAKES SENSE

Dr. Earl S. Stein
FAA, William J. Hughes Technical Center
Atlantic City International Airport, New Jersey

Research in medicine and social sciences often involves the participation of human participants, who under the rules in place today volunteer their time and understand both the benefits and risks associated with the research. This was not always the case. Rules, regulations, and laws currently require oversight by organizations referred to as Institutional Review Boards (IRBs). These boards exist to protect the participants, ensure their ethical treatment, and encourage good research. IRBs enhance the quality of research planning, and the IRB process should be part of every researcher's timeline for completion of his/her projects.

Research involves a systematic search for a reality that transcends our concepts as individuals. While philosophers will debate that there are many realities, in science we attempt to narrow the options. In social science we usually state our conclusions in probabilistic terms, admitting that there is some chance we could be wrong.

We base our conclusions on data gathered from the systematic study of some phenomenon such as behavior. We have and still study the behavior of animals and then make comparative assumptions about how their conduct may mirror our own actions. In some cases this is necessary, because it would be considered unreasonable or unethical to conduct certain studies with human beings. However, such ethics or rules of scientific morality have not always been followed and under some socio political conditions they have been ignored entirely in the misguided belief that science transcends all.

We collectively tend to forget about the "good old days" when researchers could pretty much do whatever they wanted in the name of science. There was no oversight and no IRBs. Those were the days when humans could be put at risk without knowing what the risks were, or in some cases that they were even participating in a research project. Most researchers followed their professional ethical codes and remained within the scope of law at the time. Some did not. Many walked the fine line in between. This led to notable examples which made the media in the 50's and 60's because of disastrous results.

There are many citations concerning research gone too far. The sources, themselves, can sound at times like reactionary paranoia from anti-research or anti-government organizations. For example, Smith (1998) noted "since World War II, the United States Government, mainly the Central Intelligence Agency, has secretly and at times inhumanely sought a way to control human behavior"(p. 1). Dr Frank Olsen, a Department of Defense employee, was a notable example of the CIA's LSD research program. He was given LSD without informed or any other consent; it led to depression and his suicide (Elliston, 2004). The US Army also experimented with LSD and a psychoactive gas, quinuclindnyl benzilate (BZ), from 1955 to 1975 at Edgewood Arsenal Maryland, on soldier "volunteers", who were told they would experience transitory discomfort and could terminate the experiment any time they wished but only with the consent of the physician in charge (Edgewood Guinea Pigs, 2004). This was not exactly informed consent as we know it today.

Other organizations also conducted experiments that today we would likely find unacceptable. Universities participated under grant or contract relationships with the government. In 1977, testifying before a Senate committee Admiral Stansfield Turner, then director of the CIA, admitted that his agency has participated in research involving drugs and other "mind" altering methods (Turner, 1977). While this work took place before he became director, he agreed to notify all living participants but debated about notifying participating universities in that public knowledge of the work could damage their reputations.

This is not to say that this work went on with no ethical code or rules in place. They did exist but were somehow overlooked or set aside, no doubt in part under the premise of national security. The National commission for the protection of Human Subjects was established by the National Research Act in 1974. The Tuskegee Syphilis Study was one of the factors that helped create this law.

In the Tuskegee Syphilis study. poor African American men with the disease were left untreated so researchers could follow the progress of the disease. They were not informed volunteers. The following quote is from the Centers for Disease Control Website:

"The Tuskegee Syphilis Study, carried out in Macon County, Alabama, from 1932 to 1972, is an example

of medical research gone wrong. The United States Public Health Service, in trying to learn more about syphilis and justify treatment programs for blacks, withheld adequate treatment from a group of poor black men who had the disease, causing needless pain and suffering for the men and their loved ones" (CDC, 2005, p. 1).

In part to help comply with the National Research Act, the Department of Health Education and Welfare commissioned a group of researchers and ethicists to meet at the Belmont Conference Center of the Smithsonian Institution. Their mission was to define the ethical principles and guidelines necessary for future human based research (NIH, 1979). The Belmont report summarizes the key ethical principles that the commission identified.

This work grew out of the Nuremberg code, which evolved from the trials of the same name, and was originally a method of judging physicians and other scientists who participated in research during World War Two. The conferees noted that ethics is all about boundaries and what constitutes reasonable behavior as compared to that which is deemed unethical.

The authors of the Belmont report made a clear distinction between research and practice in both medical and behavioral research. Practice involves interventions designed to improve the condition or well being of a patient or client. Research is about testing hypotheses, drawing conclusions, and advancing the body of knowledge. If research and practice occur in the same setting, or if there is any doubt as to whether research is an element in the overall program, human review for the protection of participants is required.

There are three general principles around which research ethics should be based: respect for persons, beneficence and justice.

Respect for persons is an acknowledgement that each individual is autonomous and has a right to consent or not. Part of this is to determine whether the individual has the ability to understand and if in diminished capacity extra protection is required. *Beneficence* is a principle that infers as researchers we should do no harm and both maximize the benefits and minimize the risks associated with the research. This may require a balancing of the potential rewards of doing the research against the potential risks to participants. The last principle is *justice*. Do members of the population have an equal chance of being selected for participation or does the burden of participation fall on a subgroup based on who they are or how much they have? According to the American Psychological Association (APA) (2002) in their outline of the ethical principles for psychologists, "justice" implies that psychologists ensure to their best efforts that everyone can benefit from the processes, procedures, and services they offer. As well, they must avoid the impact of their own biases and their own limitations in competence and experience so that unjust practices (i.e. the Tuskegee Syphilis Study) do not occur ever again.

The three general ethical principles are implemented through application in research. *Informed consent* is the application of respect for persons. APA calls this the respect for people's rights and dignity or Principle E. According to the Belmont report, informed consent has three parts: information, comprehension and voluntariness.

Information is provided which is accurate and sufficient so that a "reasonable volunteer" can clearly understand the risks and benefits. Incomplete disclosure is only allowed if complete information would bias or materially change the study, all risks are still disclosed, and there is a plan for debriefing participants after the data is collected.

Comprehension is the second key element. Information is provided in a manner and pace that facilitates understanding and if necessary, the researcher is obligated to test for comprehension either verbally or in writing. The third element is *voluntariness*. Participation must be truly voluntary and not coerced in any way. The research cited from Edgewood Arsenal where participants could only leave with permission did not begin to meet that criterion. We would also not want to see the type of influence that researchers can have as found by Stanley Milgrim (1974) in his work on obedience to authority. Deception was used and no aftercare plan for participants was conceived or implemented. The main lesson that came out of Milgrim's work was that ordinary people would do extraordinary things given the right social pressures in an environment labeled as research.

The Belmont conferees noted that the second application of the principles involves the assessment of risks and benefits. This is based on beneficence. Is the study worth doing given the potential outcomes weighted against the actual risks for participants? By risks they mean more than a probability but the nature and extent of harm that could befall a participant. These include both the psychological and the physical. A review committee can also consider the long term benefits of the research that may go beyond those for the individual participant and the costs of not doing the research and the loss of those benefits.

The University of Michigan Medical Institutional Review Board website (2004) commented as follows on the Belmont report:

> "The Belmont Report, as monumental as it may be, did not make specific recommendations for administrative action by the Secretary of Health, Education and Welfare; rather, it recommended that the report be adopted in its entirety, as a statement of the Department's Policy. What dignity, what statesmanship! The Belmont Report laid three basic ethical principles: "Respect for persons. Beneficence. Justice." Respect for persons; beneficence; justice. How simple, how fundamental, how awesome; not just for research involving human subjects, but for everything we do every day."

While the Belmont report was basically an outline with recommendations, the rules it recommends are codified in Federal Law (DHHS, 1983). Under 45 CFR 46 the guidelines for use of human subjects (participants) are specified and the role of Institutional Review Boards is defined. The Department of Transportation is covered specifically under 49 CFR 11 and this is a word for word copy of the DHHS regulation. The regulation clarifies what constitutes research, whether or not human beings are research subjects and also notes that even if 45 CFR 46 does not apply, other Federal, state and local laws may come into play.

Recently the Office of Human Research Protections, which is part of DHHS, published a series of decision charts designed to assist researchers and Institutional Review Boards in making decisions concerning Research proposals. Figure 1 is presented as an example (DHHS, 2004 September).

The Federal regulations and laws apply to all research funded by the, or accomplished within the Federal government. Other state and Federal laws may apply as well. Further, most professions involved in human research have ethical codes which in some ways are as stringent as Federal Law. Those of us in Psychology adhere to the APA Ethical Code or one similar to it. In the Federal Aviation Administration we have FAA Order 9500/25 which essentially mirrors 45 CFR 46 up to subparagraph 124 then goes on to offer additional protections for other specified subgroups of potential populations, such as prisoners with whom FAA researchers generally do not work (DOT, 2004). These regulations require the existence and operation of Institutional Review Boards or IRBs.

The IRB is where the researcher using human participants (note the not so subtle change from "subject" which is the term most regulations use) meets the Institutional requirements as specified in law and regulations. Many researchers including this author have at one time or another viewed the IRB by whatever title (i.e. peer review committee in Universities) as basically an impediment, a roadblock, and other terms, some even stronger, to imply that IRBs hold them up and ask them to do unreasonable things. A number of authors writing about IRBs have commented that in addition to evaluating participant safety and confidentiality IRBs should evaluate what would be lost or the cost of not doing the research that they may disapprove (Rosnow, Rotheram-Borus, Ceci, Blanck, Koocher, 1993; Rosenthal, 1994). The Belmont report had implied this as well.

IRBs are made up of people who are in many ways very much like the folks who must staff their research plans with the boards. The laws and regulations specify the general membership of an IRB. Each board must have at least five members of varied backgrounds. It can not consist of only members of one profession. The board can not be all men or women. It must include at least one member whose primary interests are in science and one member whose interests are outside of science. Members may not review research proposals in which they may have a conflict of interest.

The FAA's rules for membership are even more specific than those of the Federal Law: (1) One member who is a physician, with clinical experience or specialization in aerospace medicine. (2) One member with expertise in the behavioral and social sciences. (3) One member who is not an employee of FAA, with expertise in ethics. (4) One member with expertise in safety or industrial hygiene (in addition to review of research protocols, this member also shall, at the direction of the IRB Chair, conduct on-site inspections to assess overall safety of the proposed research projects). 5) One member representing the FAA Chief Counsel.

Currently the FAA has two IRBs. The primary IRB, which covers the entire FAA, is based in Oklahoma City. There is also a local IRB which operates at the

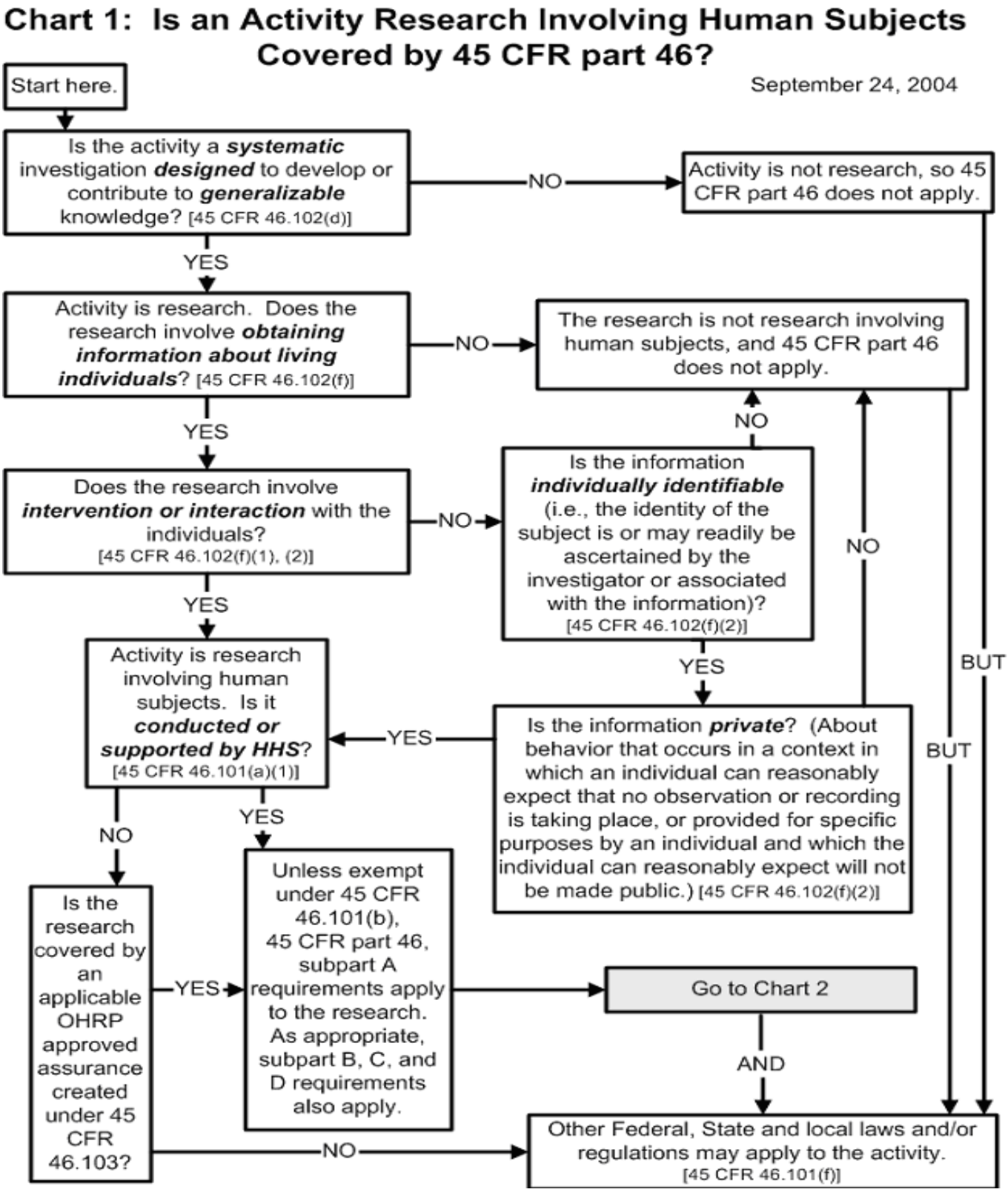

Figure 1. *Decision Support Chart*

FAA Technical Center. The local IRB handles only those research proposals that fit under minimal or no risk standards. Fortunately, this covers most of the research done at or for the Technical Center. The local IRB has a membership which meets all of the legal and regulatory requirements specified above. The physician is a local private practice internist who is a certified flight surgeon. The ethicist who is not directly affiliated with the FAA is a Chaplain with the New Jersey Air National Guard Wing based at Atlantic City International Airport.

One criticism of IRBs in general is that they are inconsistent. Rosnow et al. (1993) reported that one research plan was approved by an IRB at one university and disapproved by another university in the same community. Sure, this can happen. At least within the FAA IRBs, we are all following the same regulation with the same intent of not stopping research but rather promoting better, ethically based, and well planned research.

The purpose of the IRBs is not and was never to impede good research. IRBs are there to ensure the safety of participants and verify that a volunteer is a volunteer who really knows what he or she is getting into and knows what the risks are. The IRB is also there to ask the question, "Are the risks worth the benefits of the research?" IRB members are encouraged to ask what would be lost if the research was not conducted.

The existence of IRBs encourages (some might say forces) researchers to plan carefully and to use planning tools such as check lists to avoid missing some key points in the planning process. For example, do they intend to sample from a special population such as children or prisoners that require additional protections and scrutiny? We do not see this much or at all in the FAA. However, the plan has to have an informed consent statement and agreement that is clear and well written. If it does not, we do send it back, even if informed consent is described in the body of the plan.

This is not done to annoy the researchers. They did have a copy of the guidelines and checklist, which forms the cover sheet on our local board's application package. Further, the IRB process encourages the researcher to know the population from which he or she is sampling, so that they are reasonably certain when someone agrees to participate, informed consent is truly informed and not an attempt to please the researcher.

IRBs are not enforcement organizations. They exist to provide a means for researchers to comply with the law and regulations. It is up to management within Federal organizations and the FAA in particular to enforce the adherence to the requirements. If managers and researchers do not comply, they risk sanctions if something should go wrong in a study, and they have not followed the rules in preparation for the research. The key is to plan so that the probability that things go wrong is low and a reasonable person would not have foreseen the problem as likely to occur.

There are a number of advantages for researchers to not only accept the IRB process as a fact of their research lives but to embrace it. It allows them to comply with the law and regulations. It increases the probability that all bases are covered so that the level of risk or lack thereof, they believe exists, is in fact the level of risk present during the study. This protects the institution and the individual researcher. It ensures that the research is being done in an ethical way and participants know what they are getting into when they grant informed consent. These are definitely good results. Yes, the IRB adds time to the planning process for a study, but you can include that in your overall plan. It should not be a surprise to anyone.

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